

What is claimed is:

1. An automated process for making a gastro-retentive device, said process comprising:

- (A) providing a strip of pouch assemblies, wherein substantially each of said pouch assemblies comprises an ingredient section sealed within a membrane;
- (B) separating a pouch assembly from said strip;
- (C) folding said membrane to form a folded pouch assembly;
- (D) providing first and second capsule sections;
- (E) inserting said folded pouch assembly into said first capsule section to form a pouch/first capsule section assembly; and
- (F) combining said pouch/first capsule section assembly with said second capsule section to fully encapsulate said pouch assembly.

2. An automated process for making a gastro-retentive device in accordance with claim 1 wherein said pouch assembly has at least one flap formed by said membrane extending from said ingredient section of said pouch assembly, and step(C) further comprises the step of wrapping said flap around said ingredient section.

3. An automated process for making a gastro-retentive device in accordance with claim 2 wherein step (C) comprises the following steps for wrapping said flap:

- (i) placing said pouch assembly on a tooling block having a surface and a pocket formed therein which is sized for receiving said pouch assembly, said pouch assembly being positioned over said pocket with said flap extending away from said ingredient section; and

(ii) pushing said ingredient section of said pouch assembly into said pocket so as to fold said flap relative to said ingredient section.

4. An automated process for making a gastro-retentive device in accordance with claims 2 or 3 wherein step (E) comprises pushing said folded pouch assembly through a passageway connected to said pocket into said first capsule section.

5. An automated process for making a gastro-retentive device in accordance with any of claims 2 to 4 wherein step (F) comprises pushing said pouch/first capsule section through said passageway into said second capsule section.

6. An automated process for making a gastro-retentive device in accordance with any of claims 2 to 5 wherein at least two said steps (A) through (F) are carried out at different locations, said pouch assembly being advanced to each of said locations by a moveable surface.

7. An automated process for making a gastro-retentive device in accordance with claim 6 wherein said moveable surface comprises a table that indexes in a rotational manner to move said pouch assembly to each of said locations.

8. A process for making a gastro-retentive device having at least the following components: 1) an ingredient section, 2) a membrane surrounding the ingredient section so as to form a pouch having at least one flap extending from the ingredient section (the ingredient section in combination with the membrane referred to as a "pouch assembly"), and a capsule surrounding the pouch

assembly and which is capable of disintegrating upon contact with bodily fluids to release the pouch assembly, said capsule having first and second capsule sections; said process comprising the following automated steps:

- (A) providing a pouch assembly;
- (B) placing said pouch assembly on a tooling block having a surface and a pocket formed therein which is sized for receiving said pouch assembly, said ingredient section of said pouch assembly being placed over said pocket with said flap extending away from said pocket;
- (C) folding said flap by pushing said ingredient section of said pouch assembly into said pocket so as to fold said flap around said ingredient section;
- (D) inserting said pouch assembly folded in step (C) into the first capsule section to form a pouch/first cap assembly; and
- (E) connecting said pouch/first capsule assembly to the second capsule section to fully encapsulate said pouch assembly.

9. The process for making a gastro-retentive device of claim 8 further comprising the steps of:

- (A) (i) providing a strip of said pouch assemblies; and
- (A) (ii) separating a single pouch assembly from said strip.

10. The process for making a gastro-retentive device in accordance with claims 8 or 9 wherein step (C) further comprises the step of:

- (C) (i) moving a member over the surface of said tooling block to fold said flap extending out of said pocket.

11. The process for making a gastro-retentive device of claim 10 wherein step (C) further comprises the step of:

(C) (ii) moving a second member over the surface of said tooling block to fold a second flap extending out of said pocket.

12. The process for making a gastro-retentive device in accordance with any of claims 8 to 11 wherein step (E) comprises the step of moving said folded pouch assembly through a passageway into said first capsule section, said passageway extending through said tool block and is connected to and positioned below said pocket, said pouch assembly being moved into said passageway through said pocket during step (C).

13. The process for making a gastro-retentive device in accordance with claim 12 wherein step (F) comprises the step of moving said first capsule section/folded pouch formed in step (E) through said passageway of said tool block into said second capsule section.

14. The process for making a gastro-retentive device in accordance with any of claims 8 to 13 wherein at least two of said (A) through (E) take place at different work stations.

15. The process for making a gastro-retentive device in accordance with claim 14, wherein multiple said tooling blocks are provided, and wherein each of said tooling blocks are moved to each of said locations for carrying out the process steps.

16. An apparatus for the manufacture of a gastro-retentive device having at least the following components: 1) an ingredient

section, 2) a membrane surrounding the ingredient section so as to form a pouch that has at least one flap extending from said ingredient section (the ingredient section in combination with the membrane referred to as a "pouch assembly"), and a capsule surrounding the pouch assembly and which is capable of disintegrating upon contact with bodily fluids to release the pouch assembly, said capsule having first and second capsule sections; said apparatus comprising the following:

a tooling block having a passageway there through and which is configured for slidable movement of said pouch assembly therein, and a tooling pocket configured for receiving said pouch assembly extending from a surface of said tooling block to said passageway;

a first push member disposed to push said pouch assembly through said tooling pocket into said passageway;

at least one folding member for folding any section of the flap of said pouch assembly extending from said passageway of said tooling block, said folding member being controllably moveable relative to said tooling block; and

a second push member disposed for pushing said pouch assembly through said passageway into said first cap section.

17. An apparatus in accordance with claim 16 further comprising a third push member disposed for pushing said pouch assembly through said passageway into said second cap section.

18. An apparatus in accordance with claims 16 or 17 further comprising a cutter disposed for cutting the pouch assembly from a strip of said pouch assemblies.

19. An apparatus in accordance with any of claims 16 to 18

further comprising multiple work stations where various manufacturing processes are carried out, and wherein said tooling block is carried on a movable surface for transporting said tooling block to each of said work stations.

20. An apparatus in accordance with claim 19 further comprising multiple said tooling blocks carried on said moveable surface, said moveable surface transporting each of said tooling blocks to each of said work stations.

21. An apparatus in accordance with claims 19 or 20 wherein said moveable surface comprises a rotateable table that moves along a circular path, said work stations being stationary and positioned around a circumference of said table.

22. An apparatus in accordance with any of claims 16 to 21 wherein said passageway has at least two sections of different diameters.

23. An apparatus in accordance with any of claims 16 to 22 further comprising an arm slidable over said pocket to fold said flaps.

24. An apparatus in accordance with any of claims 16 to 23 wherein said first push member comprises a ram, and said second push member comprises a push rod.

25. A tooling block for use in the manufacture of a gastro-retentive device having at least the following components: 1) an ingredient section, 2) a membrane surrounding the ingredient section so as to form a pouch that has at least one flap

extending from said active ingredient section (the ingredient section in combination with the membrane referred to as a "pouch assembly"), and a capsule surrounding the pouch assembly and which is capable of disintegrating upon contact with bodily fluids to release the pouch assembly, said capsule having first and second capsule sections; said tooling block comprising the following:

- a surface;
- a front end;
- a back end;

a passageway extending through said tooling block from a front opening in said front end to a back opening in said back end, said passageway being configured for slidable movement of said pouch assembly therein; and

a tooling pocket extending from said surface of said tooling block to said passageway and which is configured for receiving said pouch assembly, said tooling block being configured such that said flap extends out of said pocket when said pouch assembly is placed through said tooling pocket into said passageway.

26. A tooling pocket in accordance with claim 25 wherein said passageway comprises at least two sections having different diameters from one another.

27. A tooling pocket in accordance with claim 26 wherein said passageway comprises a first section sized to receive the capsule body, and a second section, adjacent to said first section and smaller than an inside diameter of said capsule body, through which said pouch assembly is slid able into said capsule body.

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